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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,172	05/01/2001	Gregory G. Burrows	2357-003-03	5303

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EXAMINER

VANDERVEGT, FRANCOIS P

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 07/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/847,172	BURROWS ET AL.	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-40, 54 and 59-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-40, 54 and 59-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This application claims the benefit of the filing date of provisional application 60/200942 and is a continuation-in-part of U.S. Application Serial Number 09/153,586, which claims the benefit of the filing date of provisional application 60/064,552 and 60/064,555.

Claims 1-36, 41-53 and 55-58 have been canceled.

Claims 37-40, 54 and 59-82 are currently pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 24, 2006 has been entered.

In view of Applicant's amendment filed May 24, 2006, the following new ground of rejection has been necessitated.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 37-40, 54, and 59-82 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible or specific asserted utility or a well established utility.

Briefly, the claims are broadly drawn to a method for reducing an immune response in a subject [claims 37-40, 69-80] and treating a disease caused by antigen-specific T cells [claims 54, 59-68, 81-82]. All claims require the administration to a subject a composition comprising an MHC class II construct having an $\alpha 1$ domain and a $\beta 1$ domain, but lacking an $\alpha 2$ domain and a $\beta 2$ domain. The claims are drawn to the in vivo treatment of an immune response including (and specifically reciting in claims 59-61 and 69-71) various autoimmune diseases characterized by different disease etiologies and reactivities to various autoantigens. The claims have been amended to recite that the immune response being treated in the subject is an "epitope-specific immune response." However, given the nature of the immune response

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in an autoimmune disease, the artisan would question the utility of treating the subject for an immune response against a single epitope. The typical autoimmune subject is reactive with a variety of epitopes even on a single antigen. For example, in myasthenia gravis it has been established that about 60-70% of the autoantibodies that bind to the nicotinic acetylcholine receptor (AChR) bind to a domain on the alpha subunit known as the "main immunogenic region" (MIR). However, even this MIR-directed population is heterologous, recognizing multiple epitopes within the MIR (page 2343, column 2 of Tzartos et al. (J. Immunol. [1985] 134(4):2343-2349; V on form PTO-892, newly cited) for example). Furthermore, this leaves 30-40% of those endogenous anti-AChR to bind to undetermined immunoepitopes. While the instant claims are drawn to the use of MHC-bound epitopes versus antibody epitopes, the reference is applicable because the subject is also reactive with a variety of MHC epitopes. Equally applicable to the utility of the invention as presently claimed, Applicant is reminded that the effectiveness of treating a response to an autoantigen is dependent on several factors, the most critical of which is whether the therapy can be used to treat an ongoing autoimmune response or whether it is only effective prophylactically (Tisch et al, Proc. Nat. Acad. Sci. (USA). [1994] 91:437-438; U on form PTO-892 of record, page 437, column 2, last paragraph in particular). Typically, an autoimmune disease is diagnosed only after significant tissue damage has already occurred. Administration of antigen after pathogenic T cells have been activated may have an exacerbating effect on the disease, rather than a tolerogenic one. Another problem during the treatment of autoimmune diseases is determinant spreading during the course of the disease. The Tisch et al reference also teaches that "the high degree of specificity required for the process of clonal deletion/anergy may be limiting when dealing with diseases such as MS, IDDM, and RA, in which there are responses to several autoantigens [...] and the critical inciting autoantigen(s) is not known" (page 437, third full paragraph of column 3 in particular). Treating a subject with a single epitope for treating an "epitope-specific immune response" therefore lacks utility because the treatment of that single response in a subject with an ongoing immune condition does not address epitope spreading and may exacerbate the subject's overall condition. The specification demonstrates only that the MHC peptides and antigenic determinants of the invention were capable of stimulating T cell lines and T cells derived from the peripheral blood lymphocytes of human subjects wherein the T cells were selected to be specific for the antigenic determinant. The specification does not show that the peptides disclosed in the specification were able to inhibit the autoimmune reactivity of any T cells, either those of T cell lines or patient-derived. Furthermore, the specification does not address the phenomenon of determinant spreading and requires that the antigenic determinant

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 37-40, 54, and 59-82 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible or specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

4. No claim is allowed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
June 26, 2006

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
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